UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 12, 2021

Akero Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38944**	**81-5266573**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

601 Gateway Boulevard, Suite 350 **South San Francisco, CA** **(Address of principal executive offices)**	**94080** **(Zip Code)**

Registrant's telephone number, including area code (650) 487-6488

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On November 12, 2021, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Presents New Analysis of Phase 2a BALANCED Study Data Showing Additional Qualitative Evidence of Histological Improvement in EFX-treated NASH Patients after 16 Weeks of Treatment." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The Company today presented additional post-hoc analysis of data from the Company's Phase 2a BALANCED study in a poster at The Liver Meeting of the American Association for the Study of Liver Diseases. The analysis evaluated pre- and post-treatment biopsies in 40 EFX-treated patients from the BALANCED study. These post-treatment biopsies showed improvements in histological features of steatohepatitis in 87% (35 of 40) and fibrosis in 80% (32 of 40) of EFX-treated patients after 16 weeks of treatment. Patterns of disease regression were evident in many patients who did not meet the categorical thresholds for either NASH resolution without worsening of fibrosis or at least a one-stage improvement in fibrosis without worsening of NASH. Moreover, two target populations at elevated risk of NASH progression—carriers of the PNPLA3 risk allele (I148M) and/or those with Type 2 diabetes—showed comparable qualitative and/or quantitative histological improvements to the rest of the patients in the BALANCED study.

Forward-Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding Akero's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; Akero's Phase 2a BALANCED study, including results and post-hoc analysis of its data; and the potential impact of COVID-19 on strategy, future operations, enrollment and clinical trials.

Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of COVID-19 on Akero's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties and other important factors in Akero's other filings and reports with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Akero Therapeutics, Inc. on November 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 12, 2021

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer

Exhibit 99.1

Akero Presents New Analysis of Phase 2a BALANCED Study Data Showing Additional Qualitative Evidence of Histological Improvement in EFX-treated NASH Patients after 16 Weeks of Treatment

Most EFX-treated patients with end-of treatment biopsies showed improvements in features of steatohepatitis (35 of 40; 87%) and/or fibrosis (32 of 40; 80%), after only 16 weeks

Histological improvements were evident across all types of patients, including those at higher risk of progressing to advanced stages of NASH

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic biotechnology company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, today announced a new, blinded, post-hoc analysis of its Phase 2a BALANCED study of efruxifermin (EFX) in biopsy-confirmed patients with non-alcoholic steatohepatitis (NASH), which will be presented in a poster at The Liver Meeting of the American Association for the Study of Liver Diseases (AASLD), Nov. 12-15, 2021.

The analysis, entitled “Characterization of Histologic Patterns of Improvement Following Treatment With Efruxifermin (EFX) in NASH Patients With Fibrosis,” evaluated pre- and post-treatment biopsies in 40 EFX-treated patients from the BALANCED study. These post-treatment biopsies showed improvements in histological features of steatohepatitis in 87% (35 of 40) and fibrosis in 80% (32 of 40) of EFX-treated patients after 16 weeks of treatment.

Patterns of disease regression were evident in many patients who did not meet the categorical thresholds for either NASH resolution without worsening of fibrosis or at least a one-stage improvement in fibrosis without worsening of NASH. For example, some patients achieved resolution of hepatocyte ballooning without complete resolution of NASH, and some patients with bridging fibrosis (F3) showed evidence of features of fibrosis regression (e.g. interrupted septa) without complete reversion to a lower, non-bridging stage. These and other qualitative improvements, which are consistent with previously reported reductions in categorical scores, provide further evidence of the potential rapidity of EFX’s disease modifying activity.

“More than 80% of biopsied patients treated with EFX showed signs of histological improvements after only 16 weeks of treatment with EFX. The observed trends highlight the potential to achieve higher response rates after longer periods of treatment, based on the categorical endpoints accepted for use in Phase 3 trials,” said Kitty Yale, chief development officer of Akero. “We are eager to see the histology results after treatment for 24 weeks or more in the ongoing Phase 2b studies with EFX.”

The BALANCED study was a randomized, placebo-controlled Phase 2a trial that enrolled 80 biopsy-confirmed, pre-cirrhotic NASH patients (F1 to F3 fibrosis stage) who received either placebo or EFX for 16 weeks as a weekly subcutaneous injection in one of three doses: 28 mg, 50 mg, or 70 mg. Of the 40 EFX-treated patients who received end-of-treatment biopsies, 48% achieved a one-stage improvement in fibrosis without worsening of NASH, and 48% achieved NASH resolution without worsening of fibrosis. These two endpoints remain the FDA-recommended endpoints for Phase 3 clinical trials in pre-cirrhotic NASH patients.

The analysis presented at AASLD was proposed by Cynthia A. Behling, M.D., Ph.D., a liver pathologist at Pacific Rim Pathology Medical Group in San Diego who was the central reader for the BALANCED study, based on her assessments of biopsies concurrent with categorical scoring and blinded to both treatment arm and biopsy sequence. The analysis provides a more detailed view of histological change than is reflected in the categorical, FDA-recommended scoring for NASH resolution and fibrosis stage. Moreover, two target populations at elevated risk of NASH progression—carriers of the PNPLA3 risk allele (I148M) and/or those with Type 2 diabetes—showed comparable qualitative and/or quantitative histological improvements to the rest of the patients in the BALANCED study.

“This qualitative analysis gives us even greater confidence in the emerging evidence of EFX’s anti-fibrotic effects and the potential for a strong performance in reaching phase 3 study endpoints with longer treatment periods,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “Taken together, this and other analyses of our data provide compelling evidence that EFX has the potential to treat many of the complex causes of NASH, as well as to treat patients at greatest risk of progression to later stages of NASH-associated fibrosis and cirrhosis.”

About Akero Therapeutics

Akero Therapeutics is a clinical-stage cardio-metabolic company developing transformational treatments for non-alcoholic steatohepatitis (NASH), a disease without any approved therapies. Akero's lead product candidate, efruxifermin (EFX), is a differentiated Fc-FGF21 fusion protein that has been engineered to mimic the balanced biological activity profile of native FGF21, an endogenous hormone that alleviates cellular stress and regulates metabolism throughout the body. EFX is designed to offer convenient once-weekly subcutaneous dosing. The consistency and magnitude of observed effects position EFX to be a potentially best-in-class medicine, if approved, for treatment of NASH. EFX is currently being evaluated in two Phase 2b clinical trials: the HARMONY study in patients with F2/F3 advanced fibrosis and the SYMMETRY study in compensated cirrhotic (F4) patients. Akero is headquartered in South San Francisco. Visit us at www.akerotx.com for more information.

Forward-Looking Statements

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Investor Contact:
Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina.tartaglia@sternir.com